IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number	:	10/734,161	Confirmation No.:	2165
Applicant	:	Kevin T. FOLEY		
Filed	:	December 15, 2003		
Title	:	METHOD FOR PERCUTANEOUS SURGERY		
TC/Art Unit	:	3738		
Examiner:	:	David H. WILLSE		
Docket No.	:	64118.000045		
Customer No.	:	21967		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. KEVIN T. FOLEY UNDER 37 C.F.R. § 1.132

1. I, Kevin T. Foley, am a citizen of the United States residing at 2877 Keasler Circle, West, Germantown, Tennessee 38139.

2. I am the first named inventor on the patent application identified above, U.S. Application No. 10/734,161 (hereinafter "the '161 Application").

3. I am also the first named inventor on U.S. Patent No. 5,792,044 (hereinafter "the '044 Patent"), to which the '161 Application claims priority.

4. I received a Doctor of Medicine degree and completed my neurosurgery residency at the University of California at Los Angeles. Following my residency, I served in the United States Army Medical Corps as Chief of Neurosurgery at Tripler Army Medical Center and Chief of Neurosurgery at Walter Reed Army Medical Center. In 1992, I left the military to enter private practice and pursue an academic career. In addition to a full-time spine surgery practice, I am actively involved in research in image-guided spinal navigation, minimally invasive spine surgery, and spinal biomechanics. I have authored 20 book chapters and more than 75 journal publications. I have lectured at more than 100

scientific meetings and educational workshops and I have been a visiting professor and invited lecturer at several universities in the United States and abroad. I am currently a Professor of Neurosurgery and an Associate Professor of Biomedical Engineering at the University of Tennessee, Memphis.

5. A person skilled in the art of the '161 Application would have a thorough understanding of the principles of internal spinal fixation and would be experienced in the use of spinal fixation devices in surgical procedures and/or the mechanical design of internal spinal fixation devices. The person skilled in the art would either be a surgeon with at least 3 years of experience in performing spinal fixation surgery or a design engineer with at least 5 years of experience in designing spinal fixation devices.

6. I understand that Claim 1 of the '161 Application recites:

> 1. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:
> inserting a cannula into the patient;
> inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;
> inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and
> inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.

7. I understand that claim 5 of the '161 Application recites:

> 5. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:
> inserting a cannula into the patient;
> moving a fusion device through the cannula and inserting the fusion device between first and second vertebrae of the patient;
> inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;
> inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra; and

inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.

8. I understand that claim 7 of the '161 Application recites:

7. A method of fixing vertebrae of a patient together at a surgical site, the method comprising the steps of:
inserting a cannula into the patient;
expanding the cannula;
inserting a first fixation element through the cannula and securing the first fixation element to a first vertebra;
inserting a second fixation element through the cannula and securing the second fixation element to a second vertebra;
inserting a third fixation element through the cannula and securing the third fixation element to the first and second fixation elements.

9. I understand that claim 9 of the '161 Application recites:

9. A method of fixing vertebrae of a patient together at a surgical site comprising the steps of:
inserting a cannula into the patient;
moving a plurality of fixation elements through the cannula; and
installing the plurality of fixation elements at the surgical site to fix a first vertebra with respect to a second vertebra;
wherein said fixation elements include bone screws.

10. I have reviewed the Office Action dated January 3, 2006 (hereinafter "Office Action") issued by the U.S. Patent and Trademark Office in the '161 Application and the cited references (U.S. Patent No. 5,357,983 and PCT Application No. WO 02/09801 A1).

11. I understand that on page 2 of the Office Action, the Examiner alleges that "In the documents identified above, there is no discussion of two bone screws being inserted through the same inserted cannula (as opposed to separate, spaced apart cannulae, for example) and no hint of any spinal rod or plate being inserted through said cannula. . ."

12. Counsel has explained to me that it is not necessary that added claims find literal support in an application. Rather, the applicable standard is that the original

application must "reasonably convey" to a person skilled in the art such as myself that applicants were in possession of the later claimed invention.

13. In my opinion, the '161 specification reasonably conveys to a person skilled in the art such as myself that the "first," "second," and "third" fixation elements (claims 1, 5 and 7) or the "plurality of fixation elements" (claim 9) would all be inserted through a cannula in a method of fixing vertebrae of a patient together at a surgical site.

14. Contrary to the Examiner's assertion, the specifications of the '044 Patent and '161 Application clearly disclose these features.[1] For example, in numerous instances, the '044 Patent states that the entire surgical procedure can be performed through a single cannula.

15. In fact, the specification makes clear that the ability to carry out multiple manipulations using multiple tools and instruments is one of the features of the invention that is "particularly advantageous," as it states at column 7, lines 53-60, that "The present invention is particularly advantageous because the working channel 25 will simultaneously accept a plurality of movable instruments. No other known prior art device has a working channel that accepts more than one movable instrument at a time through a single port. Therefore, according to this invention, an entire percutaneous surgical procedure can be performed through the working channel 25 of the device 10 . . ."

16. The specification of the '044 Patent also clearly discloses insertion of multiple vertebral fixation elements through the single working channel cannula and attaching them to the vertebrae.

[1] Because the relevant portions of the specifications of the '044 Patent and the '161 Application are the same, the remainder of this Declaration will refer only to the '044 Patent.

17. In particular, the '044 Patent specifically discloses "The insertion of vertebral fixation elements" through the device (column 15, lines 3-4). At the time that the '044 Patent was filed (March 22, 1996), the term "vertebral fixation elements" would have been interpreted by one skilled in the art to mean elements or components of vertebral fixation systems, including at least bone screws, fixation plates and rods. Vertebral fixation elements, including bone screws, fixation plates and rods, were well known in the art at that time. For example, the Proposed Rule and Comment of the U.S. Food and Drug Administration (FDA) for Classification, Reclassification an Codification of Pedicle Screw Spinal Systems, 60 Fed. Reg. 51946-51962 (October 4, 1995) (hereinafter "FDA Publication") (attached hereto) cites numerous articles that disclose fixation systems comprising bone, screws, fixation plates, rods and other fixation elements.

18. The specification of the '044 Patent describes a particular type of vertebral fixation element that is always used in combination with other vertebral fixation elements. In particular, a pedicle screw is a fixation element that is always used in combination with a second anchoring-type fixation element (*e.g.*, a second pedicle screw or a hook) secured to a second vertebra and another fixation element, such as a plate or rod, that is secured to the first and second fixation elements. At the time that the '044 Patent was filed, it was well known in the art to secure a first fixation element such as a pedicle screw to a first vertebra, secure a second fixation element such as another pedicle screw to a second vertebra, and secure a third fixation element such as a plate or rod to the first and second fixation elements using, for example, nuts. What was not known at the time the '044 Patent was filed was that a surgeon could carry out such known surgical procedure through a single cannula. In other words, the invention of the '044 Patent resides in the recognition of conducting a surgical procedure employing multiple fixation elements through a single cannula and not in the particular order in which the surgeon inserts such elements.

19. The specification of the '044 Patent also discloses that the single cannula can be moved to different angles from a single incision site to perform the surgery. This repositioning

technique allows the surgeon to access various sites on different vertebrae with a single cannula during a surgical procedure.

20. Based on the teachings in the '044 Patent, it would have been readily apparent to one skilled in that art that the specification reasonably conveys inserting pedicle screws through a single cannula and securing them to vertebrae, inserting another fixation element such as a plate or rod through the single cannula, and securing the plate or rod to the pedicle screws. Clearly what was contemplated in the specification of the '044 Patent was a surgical procedure to install vertebral fixation elements, including two pedicle screws and another fixation element such as a plate or rod, through a single working channel cannula.

21. Referring to the citations from previous paragraphs, the specification further literally conveys to a person skilled in the art possession by the Applicants of the method of claim 9, including a cannula, multiple fixation elements, and screws included as among the fixation elements.

22. I understand that the '161 Application is assigned to SDGI Holdings, Inc., which is a subsidiary of Medtronic, Inc. ("Medtronic").

23. I have entered into an agreement with Medtronic under which I receive royalties from Medtronic based on sales of Medtronic products embodying my inventions. Under this agreement, I have received royalties for sales of Medtronic's MED™ and METRx™ products. I also act as a consultant to Medtronic and I receive compensation from Medtronic for such consulting.

24. I hereby declare that all statements made here of my own knowledge are true and that all statements made on information and belief are believed to be true and that the statements **were made with the knowledge that willful false** statements and the like are punishable by **fine or imprisonment or both under** Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any **patent issued thereon.**

Dated: 6/30/2006 **By:** _____
Dr. Kevin T. Foley